AFC/3731
JFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Jan Weber	Confirmation No.	6210
Serial No.:	10/084,857	Examiner:	Vy Q. Bui
Filed:	February 25, 2002	Art Unit:	3731
		Docket:	01-264US

Title: NON-INVASIVE HEATING OF IMPLANTED VASCULAR TREATMENT DEVICE

MS APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

We are transmitting herewith the following attached items and information (as indicated with an "X"):

X Return postcard (1).

X Appellant's Reply Brief to Examiner's Answer Under 37 CFR § 41.41 (29 pgs.).

PLEASE ASSOCIATE THIS APPLICATION WITH CUSTOMER NUMBER 38356

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: **MS APPEAL BRIEF-PATENTS** Commissioner for Patents, P.O. BOX 1450, Alexandria, VA 22313-1450, on this 6th day of July, 2006.

Shannon L. Day
Name

Signature

Respectfully Submitted,
Jan Weber

By: BROOKS & CAMERON, PLLC
1221 Nicollet Avenue, Suite 500
Minneapolis, MN 55403

Atty: Joseph C. Huebsch
Reg. No.: 42,673

July 6, 2006
Date:

Rev. 12/05

Docket No.: 01-264US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Jan Weber

Application No.: 10/084,857 Confirmation No: 6210

Filed: February 25, 2002 Art Unit: 3731

For: Non-Invasive Heating of Implanted Vascular Treatment Device Examiner: Vy Q. Bui

APPELLANT'S REPLY BRIEF TO EXAMINER'S ANSWER DATED JUNE 15, 2006

MS Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief, in compliance with 37 C.F.R. § 41.41, is in response to the Examiner's Answer dated June 15, 2006 and in furtherance of the Notice of Appeal filed under 37 C.F.R. § 41.31 on February 22, 2006.

The Examiner's Grounds for Rejection are substantially the same as those presented in the Final Office Action dated November 23, 2005. Appellant has

addressed these rejections in their Appeal Brief dated March 22, 2006. In the Examiner Answer dated June 15, 2006 the Examiner provides a response to the arguments presented in the Appeal Brief. Appellant respectfully traverses the assertions and conclusions provided in the Examiner's response. The following is the Appellant's Reply Brief.

This Reply Brief contains items under the following headings as required by 37 C.F.R. § 41.37:

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments
V. Summary of Claimed Subject Matter
VI. Grounds of Rejection to be Reviewed on Appeal
VII. Argument – Reply to Examiner's Answer
VIII. Claims Appendix
IX. Evidence Appendix
X. Related Proceedings Appendix

The final page of this brief bears the attorney's signature.

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is SciMed Life Systems, Inc. a corporation established under the laws of the State of Minnesota and having a principle place of business at One Scimed Place, Maple Grove, Minnesota 55311.

II. RELATED APPEALS AND INTERFERANCES

Appellant is unaware of any related appeal or interference.

III. STATUS OF CLAIMS

The Claims 1-2, 4-33 and 42-49 are pending. Claims 3 and 34-41 are cancelled. Claims 9, 10, 13-19, 27 and 30-33 are withdrawn. No claims are allowed. Claims 1, 2, 4-8, 11, 12, 20-26, 28, 29 and 42-49 stand rejected and are the subject of this appeal and the following response to the Examiner's Answer.

IV. STATUS OF AMENDMENTS

Appellant filed a Response after Final Rejection on January 4, 2006 (hereinafter "Final Response") with no claims amended, added, or cancelled. The Examiner responded to the Final Response with an Advisory Action mailed January 31, 2006. Appellant filed an Appeal Brief on March 22, 2006 with no claims amended, added or cancelled. This Reply Brief is in response to the Examiner's Answer to Appeal Brief dated June 15, 2006 with no claims amended, added or cancelled.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites a vascular treatment device. The device includes a stent formed with a magnetically susceptible material having a magnetic susceptibility that decreases within a preselected temperature range (page 5, lines 15-17; page 6, lines 5-16; Figure 1, element 12).

Dependent claim 2 to independent claim 1 recites that the susceptible material has a Curie temperature in the preselected temperature range (page 6, lines 5-16).

Dependent claim 4 to independent claim 1 recites that the stent includes a core, such that the susceptible material includes a coating on a surface of the core (page 8, lines 1-5 and lines 16-17).

Dependent claim 5 to dependent claim 4 recites that the coating is disposed on an external surface of the core (page 8, lines 5-7; Figure 2, element 12).

Dependent claim 6 to dependent claim 4 recites that the coating is disposed on an internal surface of the core (page 8, lines 7-9; Figure 3, element 12).

Dependent claim 7 to dependent claim 4 recites that the coating is disposed on both an internal and external surface of the core (page 8, lines 10-13; Figure 4, element 12).

Dependent claim 8 to independent claim 1 recites that the stent includes a core, such that the core is formed of the susceptible material (page 8, lines 22-24).

Dependent claim 11 to dependent claim 4 recites that the core comprises a magnetically susceptible material (page 9, lines 9-12).

Dependent claim 12 to independent claim 1 recites that the susceptible material comprises one of Ferrite Oxide (FEO) (page 6, lines 16-17) and Chromium Oxide (CrO) (page 6, lines 21-25).

In an additional embodiment, independent claim 20 recites a vascular treatment system that includes an electromagnetic field generator (page 5, lines 17-19; Figure 1, element 18). The system also includes a medical device (page 5, lines 14-16) deliverable to a treatment site (page 5, lines 14-17). The medical device includes a magnetically susceptible material being magnetically susceptible to an electromagnetic field generated by the generator and having a Curie temperature in a preselected range (page 5, lines 24-30; page 6, lines 1-20), such that the implantable device heats to a temperature sufficient to treat the treatment site when the electromagnetic field is applied (page 7, lines 21-25).

Dependent claim 21 to independent claim 20 recites that the medical device comprises a stent having a core material (page 8, lines 16-18).

Dependent claim 22 to dependent claim 21 recites that the susceptible material comprises a coating on a surface of the core material (page 8, lines 1-5).

Dependent claim 23 to dependent claim 22 recites that the coating is disposed on an external surface of the core material (page 8, lines 5-7; Figure 2, element 12).

Dependent claim 24 to dependent claim 22 recites that the coating is disposed on an internal surface of the core material (page 8, lines 7-9; Figure 3, element 12).

Dependent claim 25 to dependent claim 22 recites that the coating is disposed on both an internal and external surface of the core material (page 8, lines 10-13; Figure 4, element 12).

Dependent claim 26 to dependent claim 21 recites that the core material is formed of the susceptible material (page 8, lines 10-13; Figure 4, element 12).

Dependent claim 28 to dependent claim 22 recites that only preselected portions, less than the entire core, are coated with the susceptible material (page 11, lines 25-28).

Dependent claim 29 to dependent claim 22 recites that the core material comprises a magnetically susceptible material (page 9, lines 9-12).

Dependent claim 42 to independent claim 1 recites that the coating includes a polymer binder for the magnetically susceptible material (page 9, lines 9-12).

Dependent claim 43 to independent claim 1 recites that the core is a metal selected from the group stainless steel, Nitinol, and tantalum (page 8, lines 17-19; page 14, lines 7-8).

Dependent claim 44 to independent claim 1 recites that the coating includes a sintered coating of the magnetically susceptible material on the core (page 8, lines 1-5 and lines 16-17).

Dependent claim 45 to independent claim 1 recites that the coating includes a painted coating of the magnetically susceptible material on the core (page 8, lines 1-5 and lines 16-17).

Dependent claim 46 to independent claim 20 recites that the coating includes a polymer binder for the magnetically susceptible material (page 8, lines 13-16).

Dependent claim 47 to independent claim 20 recites that the core is a metal selected from the group stainless steel, Nitinol, and tantalum (page 8, lines 17-19; page 14, lines 7-8)

Dependent claim 48 to independent claim 20 recites that the coating includes a sintered coating of the magnetically susceptible material on the core (page 8, lines 1-5 and lines 16-17).

Dependent claim 49 to independent claim 20 recites that the coating includes a painted coating of the magnetically susceptible material on the core (page 8, lines 1-5 and lines 16-17).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The first issue is whether claims 1-2, 4-7, 20-25, 43 and 47 are unpatentable under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,364,823 to Garibaldi et al. (hereinafter "Garibaldi").

The second issue is whether claims 8, 11-12, 26, 28-29, 42, 44-46 and 48-49 are unpatentable under 35 U.S.C. § 103(a) as obvious over Garibaldi.

VII. ARGUMENT – Reply to Examiner's Answer

REJECTIONS UNDER 35 U.S.C. §102(e)

Claims 1-2, 4-7, 20-25, 43 and 47 were rejected under 35 U.S.C. § 102(e) as being anticipated by Garibaldi. Applicant respectfully traverses the rejection of the claims, and addresses their rejection as follows.

To anticipate a claim, the reference must teach each element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). It is not enough, however, that the prior art reference discloses all the claimed elements in isolation. "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The

elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Therefore, the disclosure must teach the identical invention in as complete detail as is contained in the claim, and must teach each and every claim element arranged as in the claim.

Garibaldi

Garibaldi provides methods and related devices for treating vascular defects (col. 2, lines 66-67). These include various magnetic objects that can be delivered intravascularly through a catheter (col. 3, lines 1-4). The magnetic objects include a magnetic patch that includes a hoop for ensuring the patch fully deploys (col. 3, lines 4-9). Garibaldi also provides for a liquid embolic agent with a magnetic constituent that allows the magnetic embolic agent to be controlled by a magnetic field applied by an external source magnet (Col. 3, lines 42-45).

With respect to the magnetic patch, Garibaldi provides that the patch is made from a highly flexible material such as silicon or polyurethane or some other suitable material (col. 7, lines 64-67). The patch includes "a hoop 122 of nitinol 'memory' wire, which allows the patch to be compressed to be delivered through the lumen of a catheter or by being wrapped around the distal end of the catheter" (col. 8, lines 3-6). "The hoop 122 causes the patch 120 to open to its normal (preferred round) shape. Of course some other structure or construction can be provided to cause the patch to assume its extended configuration" (col. 8, lines 6-9). Garibaldi also provides that "[t]he patch 120 includes magnetic material, for example, magnetic particles of a magnetically responsive material or a magnetic wire mesh" (col. 8, lines 9-11).

When the "patch 120" is deployed, "the hoop 122 causes the patch 120 to open to its full shape . . . [a] magnetic field . . . is then applied to the patch 120 to urge the patch against the interior of the neck of the aneurysm" (col. 8, line 19-29). Garibaldi then indicates that "[a] patch 120 can be applied to one side of a blood vessel by successive rotating the field gradient direction . . . [where] the patches

would collectively form a continuous interior wall reinforcement, like a stent" (col. 8, lines 53-59).

Garibaldi then goes on to discuss the liquid embolic agent in a section of the specification entitled "Embolic Compositions" (col. 11, line 18). In this section of the specification, Garibaldi indicates the "embolic agent of the present invention is a flowable magnetic material that can be delivered through a microcatheter, but which hardens to form a solid embolic" (col. 11, lines 19-21). This composition includes "a magnetic material dispersed in the embolic material so that the embolic material can be magnetically manipulated" (col. 12, line 17-19). "According to one aspect of this invention, the magnetic particles are preferably reactive so that they become less magnetically responsive over time . . . [t]hus the plug of magnetic embolic material will not interfere with later magnetic diagnosis and therapeutic procedures, such as MRI" (col. 12, lines 30-49).

Garibaldi goes on to indicate that:

Another way of providing a magnetically controllable embolic material that does not remain strongly magnetic after the procedure so as to interfere with subsequent diagnostic and therapeutic procedures is to use a magnetic material in the embolic that has a sufficiently high Curie temperature, that the temperature of the patient can be reduced blow the Curie temperature of the magnetic embolic material. Then after the embolic cures, the body temperature of the patient is restored, significantly reducing the magnetic properties of the embolic. (col. 13, lines 10-19)

Claim 1

In response to Appellant's arguments, the Examiner asserts that Garibaldi provides for using multiple magnetic patches for forming a continuous interior wall reinforcement, like a stent (col. 8, lines 53-61). To accomplish this, the "patch 120 includes magnetic material, for example, particles of a magnetically responsive material or magnetic wire mesh." Garibaldi indicates that food grade iron particles of about 0.5 microns to about 50 microns are a suitable magnetic material.

Garibaldi also indicates that a magnetic field is applied so as to move the patch 120 (col. 8, lines 26-32).

The Examiner further asserts that the "patches 120 have a magnetic susceptibility that decreases within a preselected temperature range and a magnetic material whose Curie point below normal body temperature can be used to make patches 120 to form a stent." To support this position, the Examiner looks to a separate and unrelated section of Garibaldi that discusses a separate and distinct embodiment of the disclosure entitled "Embolic Compositions" (starting at col. 11, line 17). So, as previously discussed in Appellant's Appeal Brief, the Examiner appears to suggest that the magnetic material in the "flowable magnetic material" of the "Embolic Compositions" could be used for the "magnetic material" of the "patch 120." Using Garibaldi in this manner, however, results in a structure that would not work for its intended purpose. As such, Garibaldi is not a suitable document on which to base an anticipatory rejection of claim 1.

As provided for herein, Garibaldi does not expressly teach that the "magnetic material" in the "Embolic Compositions" can be, or should be, used with the "patch 120." So, even though Garibaldi may disclose the claimed elements in isolation (much like a dictionary contains the words of a given novel), the reference does not expressly show the invention in as complete detail as is contained in claim 1.

One apparent reason for why Garibaldi does not expressly teach that the "magnetic material" in the "Embolic Compositions" can be, or should be, used with the "patch 120" is that the "patch 120" would no longer work as intended if the magnetic materials identified by the Examiner were used with the "patch 120." In other words, Garibaldi did not enable the embodiment of the "patch 120" suggested by the Examiner because such an embodiment is not functional.

In the section of Garibaldi entitled "Embolic Compositions," there is described a variety of what are called a "magnetically controllable embolic material" that can undergo a reduction in magnetic properties. As indicated by Garibaldi, this reduction in magnetic properties can occur due to a chemical transition of the magnetic particles (col. 12, lines 17-59), a decay process (col. 12, line 60 – col. 13, line 9), or with a magnetic material having a sufficiently high Curie temperature

(col. 13, lines 10-32). In this later embodiment, the temperature of the patient is reduced below the magnetic material Curie temperature to allow it to remain magnetic. When the body temperature of the patient is restored Garibaldi indicates that the magnetic material loses its magnetic properties.

Specifically, Garibaldi states that:

> Magnetic material whose Curie temperature are below normal body temperature (98.6 F) can be used to make the embolic material magnetic. The surrounding tissue would be sub-cooled to a temperature below this point while the aneurysm is filled and polymerization is occurring so that the material is highly susceptible to the magnetic field. When the procedure is completed the patient would be allowed to warm up to normal body temperature and the filled aneurysm would lose its ferromagnetic properties. Examples of materials with appropriate Curie temperatures are Gadolinium (15 C) and PdNi alloy (32 C). Gadolinium is presently used in MRI contrast agents, and PdNi alloy is used as passively-regulated implants that can be heated using magnetic fields. (Col. 13, lines 20-33, emphasis added).

So, at body temperatures the magnetic material of the "Embolic Compositions" has no ferromagnetic properties. In other word, the magnetic material is no longer magnetic.

Garibaldi teaches that the "patches 120" used to form the "stent" are not only applied using a magnetic field, but also that it is done at body temperature (there is no teaching in Garibaldi of "cooling" or "sub-cooling" the blood vessel prior to applying the "patches 120"). So, the "magnetic materials" identified by the Examiner in Garibaldi to be used with the "patches 120" are not magnetic at body temperature. This is why Garibaldi does not, and cannot be used, to teach the embodiment suggested by the Examiner. In other words, Garibaldi does not teach what is suggested by the Examiner because such a structure will not work for its intended purpose.

If, however, the Examiner position is that the tissues in the area of the "patches 120" are sub-cooled, the patches 120 will once again not work. For example, as provided by Garibaldi, "[i]n the preferred embodiment, the patch 120 includes a hoop 122 of nitinol . . . that causes the patch 120 to open to its normal . . .

shape" (col. 8, lines 2-7). Garibaldi also indicates that "other structure or construction can be provided to cause the patch to assume its extended configuration," but Garibaldi does not teach any other material besides nitinol that can be used to form the "hoop 122" (i.e., structure is defined as something made up of a number of parts that are held or put together in a particular way, and construction is defined as the way in which something is built or put together [The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000]). So it would appear that the "hoop 122" is only made of nitinol.

As one skilled in the art understands, nitinol is a metal that remembers its geometry. After it is deformed, it regains its original geometry by itself during heating or, at higher ambient temperatures, during unloading. Garibaldi indicates that the tissue surrounding the magnetic material having the sufficiently high Curie temperature needs to be sub-cooled so that the magnetic material can be highly susceptible to a magnetic field. However, sub-cooling the tissue in the area of the "patch 120" with this magnetic material runs counter to allowing the nitinol of "the hoop 122" to obtain its predetermined shape. For example, once the patch 120 having this magnetic material was moved under the influence of the magnetic field, the patch 120 would then be warmed to allow the nitinol "hoop 122" to expand to its preconfigured shape. Upon warming, however, the nitinol of "the hoop 122" could move the patch 120 in unpredictable ways relative to its location within the body, negating any potential benefit of having used the magnetic material having the sufficiently high Curie temperature. This provides an additional reasonable explanation as to why both Garibaldi did not arrange the elements as recited in claim 1 and why one skilled in the art would not now arrange the elements recited in Garibaldi to provide the invention recited in claim 1.

Similarly, one skilled in the art would not reasonably understand that the "hoop 122" could first be expanded under normal body temperatures followed by a sub-cooling of the surrounding tissue in order to allow the magnetic material to move under the influence of the magnetic field. As will be appreciated, when implanting medical devices in the vasculature, every precaution must be taken to prevent the medical device from being released into and possibly occluding the

blood vessel. Once released to allow the "hoop 122" to expand, the magnetic particles of the "patch 120" would not be useful in controlling the device as they would be above their Curie Point (i.e., no longer ferromagnetic). The Examiner would appear to concur with this point in the November 23, 2005 Final Office Action by asserting that "[n]otice that body temperature (98.6F) provides heat that would decrease magnetic property of stent formed with patches 120" (page 4). So, even if sub-cooling were to begin once the "hoop 122" was fully deployed, there would still likely be an unacceptable amount of time during which the "patch 120" would be outside the control of any applied magnetic forces.

The Examiner's Answer also asserted that:

> a Curie temperature is an inherent physical characteristic of a magnetic material. Therefore, when a magnetic material of stent 120 is preselected (for example, Gadolinium having Curie temperature of 15° C or PdNi having Curie temperature of 32 ° C), the associated Curie temperature of the magnetic material is also preselected. In addition, the claim only recites a preselected temperature range and not a specific range to make the claimed invention different from the Garibaldi-'823 reference. (page 6, Examiner's Answer).

Appellant respectfully notes that Garibaldi does not teach a "stent 120" as suggested by the Examiner. Rather, Garibaldi provides a "patch 120" that can be used to form a continuous interior wall reinforcement, like a stent. In addition, as discussed above, selecting the magnetic material from Garibaldi as suggested by the Examiner would lead to inoperative embodiments of the "patch 120." As discussed above, this is why Garibaldi cannot be reasonably be used to teach the identical invention in as complete detail as is contained claim 1, and why it does not teach each and every claim element arranged as in claim 1. As such, Appellant respectfully submits that Garibaldi does not support a proper anticipation rejection of claim 1, as asserted by the Examiner.

Appellant respectfully requests reconsideration and withdrawal of the §102 rejection for independent claim 1, as well as claims 2, 4-7 and 43 that depend therefrom.

Claim 20

The Examiner's Answer asserts that:

> Garibaldi-'823 (Fig. 4B, 6B, 22-23) discloses electromagnetic field B. As admitted in the specification of the present invention (line 15, page 1 to line 2, page 2), a change in the magnetizing force will result in some heat in the stent. Inherently, a change in an electromagnetic field from a zero value to B value applied to Garibaldi-'823's stent 120 will create some level of heat in stent 120. Therefore, Garibaldi-'823 inherently discloses the claimed invention.

Appellant respectfully traverses. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

Claim 20 recites that the vascular treatment system includes a medical device that heats to a temperature sufficient to treat a treatment site when an electromagnetic field is applied. So, claim 20 provides that the heat from the medical device is sufficient to treat the treatment site. In contrast, the Examiner asserts that it would be inherent in Garibaldi that electromagnetic field "B" passing through "patch 120" generated some level of heat in the device. While some heat may be generated, evidence presented by the Examiner has not made clear how one skilled in the art would recognize that the "patch 120" should be heated with the electromagnetic field "B" to a temperature sufficiently high to treat a treatment site. As such, it would appear that at best Garibaldi might provide a possibility of heating the "patch 120" to a temperature sufficiently high to treat a treatment site, but possibilities are not a sufficient basis for an inherency argument.

Appellant respectfully requests reconsideration and withdrawal of the §102 rejection for independent claim 20, as well as claims 21-25 and 47 that depend therefrom.

REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 8, 11, 26 and 29

Claims 8, 11-12, 26, 28-29, 42, 44-46 and 48-49 were rejected under 35 U.S.C. § 103(a) as being obvious over Garibaldi. Applicant respectfully traverses the rejection of the claims, and addresses their rejection as follows.

Applicant respectfully submits that a proper *prima facie* case of obviousness has not been established for claims 8, 11, 26 and 29. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

However, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

For claims 8, 11, 26 and 29, the Examiner's Answer asserted:

> Garibaldi et al.-6,364,823 discloses substantially the invention and core 122 made of a nitinol so that the medical device can open when released from a catheter. Garibaldi-'823 does not explicitly discloses the core 122 made of a magnetically susceptible material. However, Garibaldi-'823 discloses a metal gadolinium (col. 13, lines 9-33) as a magnetically susceptible material. Gadolinium

> has a high modulus of elasticity (about 76 Gpa) comparable to nitinol (about 40-75 GPa). It would have been obvious to one of ordinary skill in the art at the time to [*sic*] the invention to substitute nitinol core 122 of the Garibaldi-'823 by gadolinium core 122 so that the medical device can elastically expand when it is released from a compressed configuration. (page 4, Examiner's Answer having additional text compared to the Final Office Action dated November 23, 2005).

Appellant respectfully traverses. As discussed herein, Garibaldi provides that the patches could collectively form a continuous interior wall reinforcement, like a stent (col. 8, lines 58-59). Each of the patches "includes a hoop 122 of nitinol 'memory' wire, which allows the patch to be compressed to be delivered through the lumen of a catheter or by being wrapped around the distal end of the catheter. The hoop 122 causes the patch 120 to open to its normal (preferred round) shape" (col. 8, lines 3-7). Garibaldi goes on to indicate that "[o]f course some other structure or construction can be provided to cause the patch to assume its extended configuration" (col. 8, lines 7-9). Garibaldi does not provide any additional teaching as to what "other structure or construction" could possibly be used.

The Examiner, however, asserts that "hoop 122 of nitinol" could be replaced with the element gadolinium. Garibaldi discusses the use of the element gadolinium in conjunction with the magnetically controllable embolic material, as discussed herein (see col. 13, lines 10-17 and 29-33). However, the element gadolinium is a malleable and ductile metal that does not possess the proper elastic properties to provide the function required by the hoop 122 (i.e., the ability to cause the patch to "open"). In other words, a "hoop 122" made of the element gadolinium, as suggested by the Examiner, once compressed (e.g., bent) or wrapped around a catheter would not have the ability to "open to its normal (preferred round) shape" by itself as required by Garibaldi.

The reason for this is that gadolinium is neither a superelastic material nor is it a "shape memory" metal like Nitinol. As noted by the Examiner, the Modulus of Elasticity (or Young's Modulus (E)) for Gadolinium is approximately 76 GPa. The Modulus of Elasticity for Nitinol, however, has different values based on its crystalline phase (e.g., austenite and martensite). As is known to one skilled in the

art, the shape memory effect of Nitinol is the process of restoring an original shape of a plastically deformed sample by heating it. This is a result of a crystalline phase change known as "thermoelastic marensitic transformation." Below the transformation temperature, Nitinol is martensitic having a Young's Modulus of approximately 28 to 41 GPa. In this state, the Nitinol can be deformed from its original shape to be loaded onto, for example, the "catheter 22" of Garibaldi. At the delivery site, the body heat converts the Nitinol to its high strength austenitic condition, with a Young's modulus of approximately 83 GPa, as it transforms back to its original shape. This ability to undergo this transformation is what makes Nitinol desirable in the application proposed in Garibaldi and why gadolinium is not a suitable substitute.

In contrast to Nitinol, Gadolinium is a polycrystalline structure that does not undergo a thermoelastic transformation like Nitinol. So, once gadolinium is deformed it will not recover its original shape through the application of heat regardless of how much is applied to it. As illustrated in Garibaldi, the "patch 120" is wound around the "catheter 22" (see Fig. 12B of Garibaldi). Unlike Nitinol, Gadolinium does not possess the property of having two yield stress states (one for its austenite state and one for its martensite state). So, once the Gadolinium is deformed by bending around the "catheter 22", a "hoop 122" of gadolinium cannot return to its original shape through the application of body heat. This is most likely why Garibaldi chooses only Nitinol for this application, as it can undergo this deformation in its martensite state with the ability to recover its original shape upon transformation to the austenite state. As such, one skilled in the art would most likely not have chosen to use Gadolinium in place of Nitinol for "hoop 122" as suggested by the Examiner.

So, modifying Garibaldi as suggested by the Examiner would render the "patch 120" unsatisfactory for its intended purpose. As such, there is no suggestion or motivation to make the proposed modification as asserted by the Examiner.

In addition, as discussed above for the 102 rejections, Garibaldi does not support a proper 102 rejection of independent claims 1 and 20. As claims 8 and 11 are dependent claims of independent claim 1, and claims 26 and 29 are dependent

claims of independent claim 20, the 103 rejection of claims 8, 11, 26 and 29 should be withdrawn.

Based on the forgoing, Appellant respectfully requests reconsideration and withdrawal of the 103 rejections of claims 8, 11, 26 and 29.

Claim 12

The Examiner has maintained the assertion that even though Garibaldi does not disclose FeO (ferrite oxide) or CrO (chromium oxide) as a magnetically susceptible material, these materials are well known magnetically susceptible materials that could be used in place of a gadolinium or a PdNi. Appellant respectfully traverses and repeats the request for a document in support of this ability to substitute FeO and/or CrO for gadolinium or PdNi. Appellant makes this request based on the fact that gadolinium and PdNi where chosen by Garibaldi based on their Curie temperature (see col. 13, lines 29-31) that are not matched by FeO and/or CrO. As such, one skill in the art would not have reasonably believed that FeO and/or CrO could be substituted for gadolinium or PdNi as easily as is suggested by the Examiner. In other words, there is a specific necessary reason why Garibaldi selects gadolinium and PdNi (i.e., for their Curie temperature) that is not matched by using FeO and/or CrO.

In addition, as discussed above for the 102 rejections, Garibaldi does not support a proper 102 rejection of independent claim 1. As claim 12 is a dependent claim of independent claim 1 the 103 rejection of claim 12 should be withdrawn.

Based on the forgoing, Appellant respectfully requests reconsideration and withdrawal of the 103 rejection of claim 12.

Claim 28

Appellant respectfully submits that a proper *prima facie* case of obviousness continues not to have been established for claim 28.

For claim 28, the Examiner in the Final Office Action asserted:

> Garibaldi et al.-6,364,823 does not disclose less than the total core is coated with magnetically susceptible material. However, it would have been obvious to one of ordinary skill in the art at the time

> of the invention to coat the core with less than the total core for this configuration is only a design choice (no criticality). (pages 3-4, Final Office Action dated November 23, 2005)

The Appellant respectfully traversed this assertion, submitting that the Examiner had not provided a sufficient motivation or reason as to why one skilled in the art would have modified Garibaldi as suggested. In the Examiner's Answer, no motivation and/or reason was supplied as to why one skilled in the art would have modified Garibaldi as suggested. As such, Appellant respectfully maintains their submission that one skilled in the art would not have been motivated to provide the magnetically susceptible material on less than the entire core as this would go against Garibaldi's cited purpose of holding the "patch 120" against a vessel wall with a transverse gradient field (col. 8, lines 53-55). Appellant respectfully submits that one skilled in the art would want to maximize this holding force by providing as much of the magnetic material as possible. So coating less than the entire core would run contrary to the understanding of one skilled in the art.

The Examiner's Answer did, however, assert that while Garibaldi does not disclose less than the total core being coated with magnetically susceptible material, Doscher discloses selective coating of the stent to direct heat generation to a selective portion of the stent at column 10, lines 46-67 and in claim 21. The Examiner then asserts that it "would have been obvious to one of ordinary skill in the art at the time of the invention to coat the core less than the total core for this configuration would direct the heat generation to a selective protion [*sic*] of the stent as one desires." Appellant respectfully submits, however, that a proper motivation as to why one skilled in the art would have combined Garibaldi with Doscher has not been suggested.

As is known, there are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. As discussed above, the teaching of Garibaldi would not appear to suggest minimizing the amount of magnetic material used on the "patch 120." Also, the nature of the problem addressed in Garibaldi does not appear to warrant a reduction in the amount of

magnetic material for the reasons discussed herein. Finally, Garibaldi does not appear to provide an insight into what knowledge one skilled in the art would have motivated and/or provided the desirability to go contrary to the stated goal of applying the "patches 120" to the vessel wall with a magnetic force by reducing the amount of the magnetic material used. As provided in the M

In addition, as discussed above for the 102 rejections, Garibaldi does not support a proper 102 rejection of independent claim 20. As claim 28 is a dependent claim of independent claim 20 the 103 rejection of claim 28 should be withdrawn.

Based on the forgoing, Appellant respectfully requests reconsideration and withdrawal of the 103 rejection of claim 28.

Claims 44, 45, 48 and 49

Appellant respectfully submits that a proper *prima facie* case of obviousness has not been established for claims 44, 45, 48 and 49.

For claims 44, 45, 48 and 49, the Examiner asserted:

> Garibaldi et al.-6,364,823 discloses substantially the invention. The claims refer to a manner the coating is made, which does not provide much patentable weight to the device of the present invention. (page 4, Final Office Action dated November 23, 2005)

In the Examiner's Answer, it was asserted that "the claims recite methods of making the coating. These methods of coating will be given patentablility in method claims."

Appellant respectfully traverses the assertion that the claims "refer to a manner the coating is made." To the contrary, the claims recite a structure for the coating. For example, claims 44 and 48 recite that the coating includes "a sintered coating," (in contrast to reciting "sintering the coating . . .). Similarly, claims 45 and 49 recite that the coating includes "a painted coating," (in contrast to reciting "painting the coating . . .). Appellant respectfully submits that they are unable to find a teaching or suggestion in Garibaldi of either a sintered coating or a painted

coating, as recited in claims 44, 45, 48 and 49. As such Garibaldi does not appear to teach or suggest all the elements recited in claims 44, 45, 48 and 49.

In addition, as discussed above for the 102 rejections, Garibaldi does not support a proper 102 rejection of independent claims 1 and 20. As claims 44 and 45 are dependent claims of independent claim 1, and claims 48 and 49 are dependent claims of independent claim 20, the 103 rejection of claims 44, 45, 48 and 49 should be withdrawn.

Based on the forgoing, Appellant respectfully requests reconsideration and withdrawal of the 103 rejections of claims 44, 45, 48 and 49.

Claims 42 and 46

As discussed above for the 102 rejections, Garibaldi does not support a proper 102 rejection of independent claims 1 and 20. As claim 42 is a dependent claim of independent claim 1, and claim 46 is a dependent claim of independent claim 20, the 103 rejection of claims 42 and 46 should be withdrawn.

Based on the forgoing, Appellant respectfully requests reconsideration and withdrawal of the 103 rejections of claims 42 and 46.

The Examiner is invited to telephone Appellant's attorney, Joseph C. Huebsch, at (612) 236-0122 with regard to this matter.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: **MS APPEAL BRIEF-PATENTS** Commissioner for Patents, P.O. BOX 1450, Alexandria, VA 22313-1450, on this 6th day of July, 2006.

Shannon L. Day
Name

Signature

Respectfully Submitted,
Jan Weber

By: BROOKS & CAMERON, PLLC
1221 Nicollet Avenue, Suite 500
Minneapolis, MN 55403

Atty: Joseph C. Huebsch
Reg. No.: 42,673

July 6, 2006
Date:

VIII. CLAIMS APPENDIX

The Claims on Appeal

1. (Previously Presented) A vascular treatment device, comprising:

a stent formed with a magnetically susceptible material having a magnetic susceptibility that decreases within a preselected temperature range.

2. (Original) The vascular treatment device of claim 1, wherein the susceptible material has a Curie temperature in the preselected temperature range.

3. (Canceled)

4. (Previously Presented) The vascular treatment device of claim 1, wherein the stent includes a core, where the susceptible material comprises a coating on a surface of the core.

5. (Original) The vascular treatment device of claim 4, wherein the coating is disposed on an external surface of the core.

6. (Original) The vascular treatment device of claim 4, wherein the coating is disposed on an internal surface of the core.

7. (Original) The vascular treatment device of claim 4, wherein the coating is disposed on both an internal and external surface of the core.

8. (Previously Presented) The vascular treatment device of claim 1, wherein the stent includes a core, where the core is formed of the susceptible material.

9. (Withdrawn) The vascular treatment device of claim 4, wherein preselected portions of the core material are formed of the susceptible material and preselected portions are formed of another material.

10. (Withdrawn) The vascular treatment device of claim 4, wherein only preselected portions, less than the entire core, are coated with the susceptible material.

11. (Original) The vascular treatment device of claim 4, wherein the core comprises a magnetically susceptible material.

12. (Original) The vascular treatment device of claim 1, wherein the susceptible material comprises one of Ferrite Oxide (FEO) and Chromium Oxide (CrO).

13. (Withdrawn) The vascular treatment device of claim 12 wherein the susceptible material has a particle size less than approximately 500 nanometers.

14. (Withdrawn) The vascular treatment device of claim 1, wherein the medical device comprises:

a therapeutic agent delivery device.

15. (Withdrawn) The vascular treatment device of claim 14, wherein the delivery device includes an expandable member, self-expanding to an expanded position at a preselected temperature, and when in the expanded position the expandable member releases the therapeutic agent.

16. (Withdrawn) The vascular treatment device of claim 1, wherein the medical device comprises:

a self-expanding stent, expanding at a temperature no greater than the preselected temperature range.

17. (Withdrawn) The vascular treatment device of claim 1 wherein the medical device comprises a balloon catheter.

18 (Withdrawn) The vascular treatment device of claim 1 wherein the medical device comprises a filter.

19. (Withdrawn) The vascular treatment device of claim 1 wherein the medical device comprises a guidewire.

20. (Original) A vascular treatment system, comprising:

an electromagnetic field generator; and

a medical device deliverable to a treatment site and including a magnetically susceptible material being magnetically susceptible to an electromagnetic field generated by the generator and having a Curie temperature in a preselected temperature range, such that the implantable device heats to a temperature sufficient to treat the treatment site when the electromagnetic field is applied.

21. (Original) The vascular treatment system of claim 20, wherein the medical device comprises;

a stent having a core material.

22. (Original) The vascular treatment system of claim 21, wherein the susceptible material comprises a coating on a surface of the core material.

23. (Original) The vascular treatment system of claim 22, wherein the coating is disposed on an external surface of the core material.

24. (Original) The vascular treatment system of claim 22, wherein the coating is disposed on an internal surface of the core material.

25. (Original) The vascular treatment system of claim 22, wherein the coating is disposed on both an internal and external surface of the core material.

26. (Original) The vascular treatment system of claim 21, wherein the core material is formed of the susceptible material.

27. (Withdrawn) The vascular treatment system of claim 22, the preselected portions of the core material are formed of the susceptible material and preselected portions are formed of another material.

28. (Original) The vascular treatment system of claim 22, wherein only preselected portions, less than the entire core, are coated with the susceptible material.

29. (Original) The vascular treatment system of claim 22, wherein the core material comprises a magnetically susceptible material.

30. (Withdrawn) The vascular treatment system of claim 20, wherein the susceptible material comprises one of Ferrite Oxide (FEO) and Chromium Oxide (CrO) having a particle size of less than approximately 500nm.

31. (Withdrawn) The vascular treatment system of claim 20, wherein the medical device comprises:

a therapeutic agent delivery device.

32. (Withdrawn) The vascular treatment system of claim 31, wherein the delivery device includes an expandable member, self-expanding to an expanded position at a preselected temperature, and when in the expanded position the expandable member releases the therapeutic agent.

33. (Withdrawn) The vascular treatment system of claim 20, wherein the implantable member comprises:

a self-expending stent, expanding at a temperature no greater than the preselected temperature range.

34. - 41. (Canceled)

42. (Previously Presented) The vascular treatment device of claim 1, wherein the coating includes a polymer binder for the magnetically susceptible material.

43. (Previously Presented) The vascular treatment device of claim 1, wherein the core is a metal selected from the group stainless steel, Nitinol, and tantalum.

44. (Previously Presented) The vascular treatment device of claim 1, wherein the coating includes a sintered coating of the magnetically susceptible material on the core.

45. (Previously Presented) The vascular treatment device of claim 1, wherein the coating includes a painted coating of the magnetically susceptible material on the core.

46. (Previously Presented) The vascular treatment device of claim 20, wherein the coating includes a polymer binder for the magnetically susceptible material.

47. (Previously Presented) The vascular treatment device of claim 20, wherein the core is a metal selected from the group stainless steel, Nitinol, and tantalum.

48. (Previously Presented) The vascular treatment device of claim 20, wherein the coating includes a sintered coating of the magnetically susceptible material on the core.

49. (Previously Presented) The vascular treatment device of claim 20, wherein the coating includes a painted coating of the magnetically susceptible material on the core.

IX. EVIDENCE APPENDIX

No evidence is submitted.

X. RELATED PROCEEDINGS APPENDIX

As there are no appeals or interferences known to Appellant's Representatives which will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal. There are no copies of decisions rendered by a court or the Board to submit.